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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/781,592	02/12/2001	Beverly M. Emerson	1211.003US1	1304
54244	7590	10/05/2005	EXAMINER	
KLARQUIST SPARKMAN, LLP 121 S.W. SALMON STREET SUITE 1600 PORTLAND, OR 97204			MARVICH, MARIA	
			ART UNIT	PAPER NUMBER
			1633	

DATE MAILED: 10/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/781,592

Applicant(s)

EMERSON, BEVERLY M.

Examiner

Maria B. Marvich, PhD

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 7/20/05.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 38,40-43,46-51,53-61,63,64,66,68,72-77,79-85,87 and 88 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 38,40-43,46-51,53-61,63,64,66,68,72-77,79-85,87 and 88 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |                                                                                                                        |                                                                                         |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                            | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____                                                |

### DETAILED ACTION

This office action is in response to an amendment filed 7/20/05. Claims 1-37, 39, 44, 45, 52, 62, 65, 67, 69-71, 78, 86 and 89-99 have been cancelled. Claims 38, 40-43, 46-51, 53-61, 63, 64, 66, 68, 72-77, 79-85, 87 and 88 are pending in the application.

#### *Response to Amendment*

Any rejection of record in the previous action not addressed in this office action is withdrawn. The new grounds of rejection herein were necessitated by amendment and, therefore, this action is final.

#### *Claim Rejections - 35 USC § 112, first paragraph*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 38, 40-43, 46-51 and 53-61 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a new rejection necessitated by applicants' amendment.**

The limitation that a "multi-subunit protein complex" is formed has been added to claim 38 and 43. Applicant has not indicated where support for this limitation is found. The examiner has been unable to find literal support in the originally filed specification for a "multi-subunit

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protein complex” that is one or more subunits of the chromatin remodeling complex and the DNA binding domain peptide. The specification teaches that “multi-subunit protein complexes” are called “chromatin remodeling complexes” which as demonstrated in figure 4 is not comprised of the nucleic acid regulatory protein. Therefore, the term “multi-subunit protein complex” is given a meaning in the claims that is distinct from that in the specification. Therefore, the specification does not teach detecting an increase or decrease in the amount of “multi-subunit protein complex” as a means to detecting the interaction between the remodeling complex and DNA binding domain. Therefore, the limitation lacks description in the specification and is impermissible NEW MATTER.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 63, 64, 66, 68, 72-77, 79-85, 87 and 88 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. **This is a new rejection necessitated by applicants' amendment.**

Claim 63 recites the limitation "the test compound" in claim 63. There is insufficient antecedent basis for this limitation in the claim.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 38, 40, 43, 48, 53 and 57-61 are rejected under 35 U.S.C. 102(e) as being anticipated by Wong et al (US 6,465,629; see entire document) as evidenced by Wang et al (Cell Growth and Differentiation, 1990, pg 233-238) and as evidenced by Dahiya et al (MCB, 2000, pages 6799-6805). **This rejection is maintained for reasons of record in the office action mailed 3/16/05 and restated below. The rejection has been restated based upon applicants' amendment.**

Wong et al teach a method of screening drugs that modulate the binding of Rb, with BRG1, a chromatin remodeling subunit of SWI/SNF. Rb or retinoblastoma tumor suppressor is a nuclear regulatory protein that comprises an A and B pocket domain that interacts with chromatin remodeling subunits as well as other transcription factors such as E2F to modulate their activity. The method measures the extent of binding that is enhanced or inhibited by an agent *in vitro* (see e.g. col 27, line 52-col 29, line 3 and col 28, line 55-61). In the method, BRG1 or the nuclear regulatory protein may be tagged with a label (col 28, line 6-32). Small molecules as well as peptides can be identified that modulate the interaction between Rb and BRG1 (see e.g. col 29, line 51-56). As well, Wong teaches that ligands, which have peptide domains, interact with BRG1. The instant claims recite that the chromatin remodeling subunit is

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associated with a DNA binding domain of a nuclear regulatory protein whose direct interaction is enhanced or repressed by the test compounds. As evidenced by Wang et al a DNA binding domain of retinoblastoma is found in the C-terminus (see abstract). This region is also involved in binding to brg1 as evidenced by Dahiya et al (see e.g. figure 1). Therefore, Wong et al anticipates claims 38-40, 43, 48; 53 and 57-61 of the instant application.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 47 and 53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wong et al (US 6,465,629; see entire document) as evidenced by Wang et al (Cell Growth and Differentiation, 1990, pg 233-238) and as evidenced by Dahiya et al (MCB, 2000, pages 6799-6805) in view of Strober et al (MCB, 1996, pages 1576-1583; see entire document). **This rejection is maintained for reasons of record in the office action mailed 3/16/05 and restated below. The rejection has been restated based upon applicants' amendment.**

Applicants claim a method of screening for compounds that modulate chromatin remodeling of a specific DNA sequence within chromatin by determining chromatin remodeling the presence of BRM with a nucleic acid regulatory protein.

The teachings of Wong et al are described above and are applied as before except;

Wong et al do not teach that that the method uses BRM.

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Strober et al teach that BRM interacts with Rb to induce flat, growth arrested SW 13 cells. Following interaction of BRM with RB, glucocorticoid mediated transcriptional activation is then potentiated (see e.g. page 1577, col 1, paragraph 2). As BRG1 interaction with Rb mediates its effects through E2F, the multiple pathway options appear to present a fine regulation of transcription by utilizing a multiplicity of possible interactions (see e.g. page 1582, col 1, paragraph 3).

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to perform the assay for drugs that alter Rb binding to BRG1 as taught by Wong et al using BRM as taught by Strober et al et al because Wong et al teach that is within the ordinary skill in the art to identify modulators of Rb binding to identify drug therapies for cancer and Peterson and Lorie teach that it is within the ordinary skill of the art to assay BRM, Rb interaction. One would have been motivated to do so in order to receive the expected benefit of identifying modulators of fine regulation of transcription by affecting a multiplicity of possible interactions. Based upon the teachings of the cited references, the high skill of one of ordinary skill in the art, and absent evidence to the contrary, there would have been a reasonable expectation of success to result in the claimed invention.

### ***Response to Argument***

Applicants traverse the claim rejections under 35 U.S.C. 102 an 103 on pages 11-14 of the amendment filed 7/20/05. Applicants argue that the claims have been amended to overcome the art rejections by recitation that the compound modulates a direct interaction between a chromatin remodeling complex and a DNA binding domain peptide. Applicants argue that as

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Wong does not teach an association with E2F or its DNA binding domain, it does not anticipate the instant invention.

Applicants' arguments filed 7/20/05 have been fully considered but they are not persuasive. Wong et al teach a direct interaction between Brg1 and Rb. As evidenced by Wang et al and Dahiya et al, the interaction involves a domain that is also involved in DNA binding. Therefore, Wong et al do anticipate the instant claims.

### ***Conclusion***

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maria B. Marvich, PhD whose telephone number is (571)-272-0774. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Nguyen, PhD can be reached on (571)-272-0731. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Maria B Marvich, PhD  
Examiner  
Art Unit 1633

September 29, 2005



JAMES KETTER  
PRIMARY EXAMINER